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IS 3319 (1995): Blades, Surgical, Detachable (Bard Parker Type) and Handles [MHD 1: Surgical Instruments]



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IS 3319 : 1995

भारतीय मानक

(Reaffirmed 2006)

**बार्ड पार्कर किस्म के शल्यक वियोज्य ब्लेड
तथा दस्ते — विशिष्टि
(चौथा पुनरीक्षण)**

Indian Standard

**BLADES, SURGICAL, DETACHABLE (BARD
PARKER TYPE) AND HANDLES —
SPECIFICATION
(Fourth Revision)**

UDC 615.472.2/3

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**BUREAU OF INDIAN STANDARDS
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July 1995

Price Group 3

Surgical Instruments Sectional Committee, MHD 1

FOREWORD

This Indian Standard (Fourth Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Surgical Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1965 and revised in 1973, 1980 and 1985 to incorporate various modifications in the light of experience gained during the course of implementation of this standard and to align the fitting dimensions of blades with ISO 7740 : 1985 'Instruments for Surgery — Scalpels with detachable blades — Fitting dimensions' issued by the International Organization for Standardization, ISO. In this fourth revision:

- i) the requirements for primary packaging for sterile surgical blades including that for VCI Coated paper have been modified;
- ii) the clause providing for GO and NO-GO gauges for checking conformity of the fitting dimensions of blades and handles has been deleted;
- iii) marking details have been modified to incorporate the information relating to material and sterilization; and
- iv) the requirements for sterility, workmanship and finish have been modified.

It has to be ensured that the blades conforming to this standard are used only with those handles, whose fitting dimensions are in accordance with this standard. A separate Indian Standard covering the fitting dimensions and other requirements for handles for detachable blades is intended to be brought out in due course.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

**BLADES, SURGICAL, DETACHABLE (BARD
PARKER TYPE) AND HANDLES —
SPECIFICATION**

(Fourth Revision)

1 SCOPE

1.1 This standard specifies the requirements for detachable surgical blades (Bard Parker Type) and their handles.

2 REFERENCES

2.1 The following standards contain provisions which through reference in the text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All Indian Standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below:

<i>IS No.</i>	<i>Title</i>
4905 : 1968	Methods for random sampling
6263 : 1972	Specification for volatile corrosion inhibitor (VCI) treated paper

IS No.

Title

6911 : 1992	Specification for stainless steel plate, sheet and strip (<i>first revision</i>)
10150 : 1981	Guide for sterilization of medical products

3 TERMINOLOGY

3.0 For the purpose of this standard, the following definitions (*see also* Fig. 1) shall apply.

3.1 Nick

A chipped-out, broken-out, indented, or beat-out piece of metal, or any similar gap or indentation.

3.2 Feather

A thin, turned, projecting or curled edge not removed by honing or buffing.

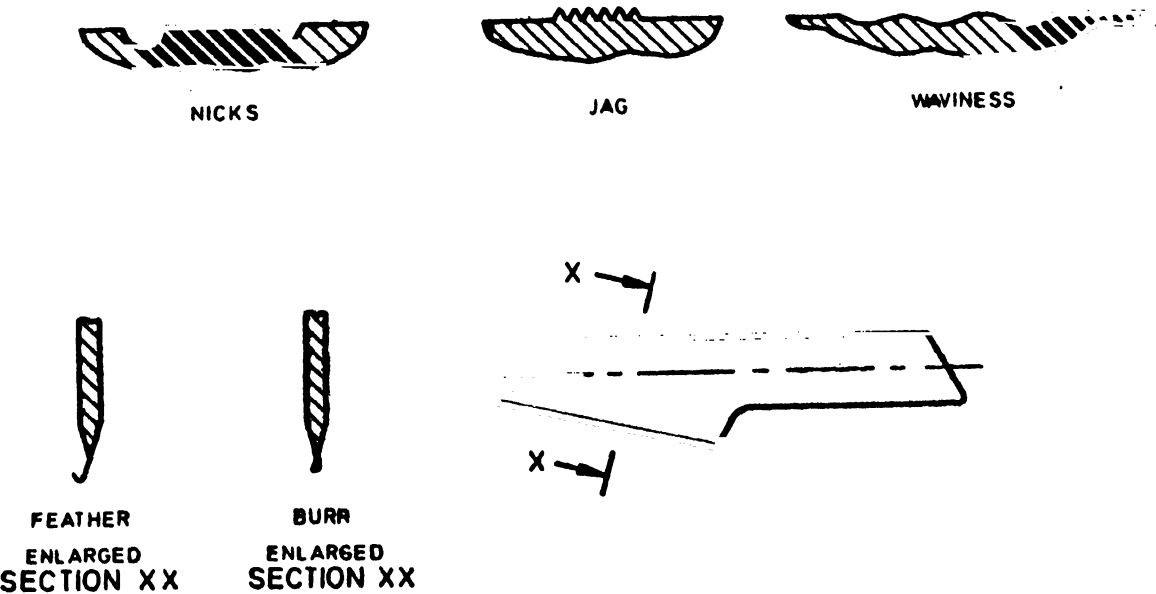


FIG. 1 DETAILS OF NICKS, JAG, WAVINESS, FEATHER AND BURR

3.3 Burr

A piece of metal projection not normally inherent to smooth uniform surface.

3.4 Waviness

Undulation of the cutting edge.

3.5 Jag

Several small tooth-like projections or similar indentations, individually smaller than a nick.

4 MATERIAL

4.1 Blade

The blades shall be made either from the carbon steel or from the stainless steel.

The carbon steel shall conform to the following composition:

Constituent	Percent
Carbon	1.10 to 1.30
Manganese	0.30 to 0.60
Chromium	0.20 to 0.50
Silicon	0.25 Max
Phosphorus	0.03 Max
Sulphur	0.03 Max

The stainless steel shall conform to designation X30Cr13 or X40Cr13 of IS 6911 : 1992.

4.2 Handle

It shall be made from stainless steel conforming to designation X07Cr18Ni9 or X07Cr17 of IS 6911 : 1992.

4.3 Packing Material

4.3.1 Aluminium foil of minimum 0.04 mm thickness and provided with a suitable heat sealing coating shall be used for primary packing. It shall pass the requirements of leakage test as per 3.5.3 of IS 10150 : 1981.

4.3.2 The volatile corrosion inhibitor (VCI) coated paper to be used shall conform to IS 6263 : 1972.

5 SHAPE AND DIMENSIONS

5.1 The dimensions of slot for blade and matching dimensions of handle shall be as given in Table 1 read with Fig. 2 and 3, for small size and Table 2 read with Fig. 2 and 3 for large size.

NOTE — The commonly used commercial designations for blades are No. 10, 11, 12, 15, 20, 21, 22, 23, 24 and 25; and for handles are No. 3, 3L, 4, 5, and 7.

5.2 The thickness of the blade shall be between 0.37 and 0.42 mm. Both surfaces of the blade and all the sides of the slot shall be uniform and free from roughness and waviness, when inspected with normal or corrected vision.

6 WORKMANSHIP AND FINISH

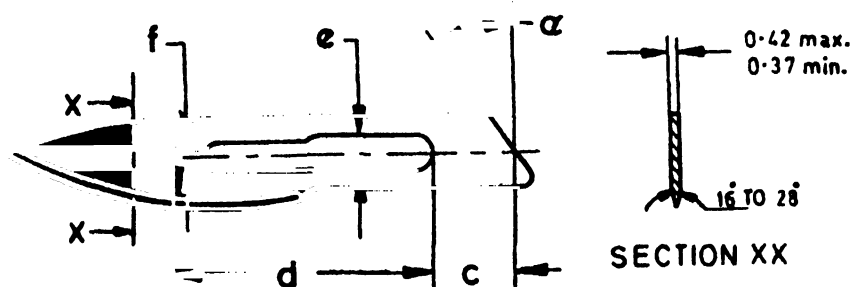
6.1 The cutting edge of the blade shall be central with respect to the thickness of the blade and it shall be in one plane, when examined with normal or corrected vision. The blade shall fit to the corresponding mount of the handle snugly. The blade shall be flat and shall not be sprung.

Table 1 Dimensions for Small Size Fittings
(Clause 5.1)

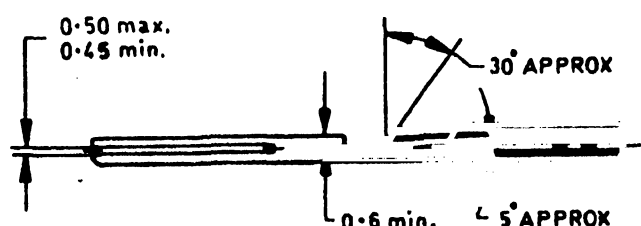
	$\pm 0.5^\circ$	c		d		e		f		l
		Min mm	Max mm	Min mm	Max mm	Min mm	Max mm	Min mm	Max mm	
Blade	30°	4.50	4.65	17.83	17.90	2.43	2.48	1.18	1.23	—
Handle	40°	4.40	4.50	17.73	17.81	2.31	2.41	1.12	1.17	9

Table 2 Dimensions for Large Size Fittings
(Clause 5.1)

	$\pm 0.5^\circ$	c		d		e		f		l
		Min mm	Max mm	Min mm	Max mm	Min mm	Max mm	Min mm	Max mm	
Blade	35°	7.50	7.65	24.20	24.27	3.72	3.77	1.95	2.00	—
Handle	35°	7.40	7.50	24.10	24.18	3.60	3.70	1.88	1.93	13



All dimensions in millimetres.
FIG. 2 DETACHABLE BLADE



All dimensions in millimetres.
FIG. 3 SCALPEL HANDLE

6.2 The tip of the blade shall be well defined, central and sharp. There shall be no waviness, jags, feathers, nicks or other defects on the cutting edge, when examined in accordance with 9.1. The surfaces of the finished blade shall be smooth and free from tool marks and any sign of corrosion. The edges other than the cutting edge, shall not be sharp.

6.3 The handle surface shall be finished smooth with bright or matt finish. The handles shall be provided with suitable grips for good hold. The grips shall have their edges suitably rounded so as not to injure the hands of the user. The handle shall be free from burrs, sharp or rough edges, pits, cracks and other surface defects. The edges of the handle shall be chamfered. Handles shall be passivated.

6.4 Prior to packing, the blades and handles shall be suitably degreased, washed and dried.

7 HEAT TREATMENT

7.1 The blade shall be hardened and tempered to give a hardness, when measured within 3 mm of the cutting edge, as follows:

For stainless steel blade	700 HV <i>min</i>
For carbon steel blade	750 HV <i>min</i>

The hardness for the rest of the blade shall be not less than 500 HV.

8 STERILIZATION

8.1 The blades shall be sterilized with ionizing radiation process. Each batch of the sterilized

blades shall satisfy the requirements of sterility, when tested in accordance with IS 10150 : 1981.

8.2 Prior to sterilization, each carton (outer container) of the blades shall be provided with a sterilization indicator (preferably a chemical indicator) on its outer surface to ensure that the contents of the package have undergone sterilization and to distinguish sterile packages from the non-sterile packages.

8.3 Prior to sterilization, a bioburden history of the finished product shall also be established and the manufacturer shall ensure that the general guidelines laid down in IS 10150 : 1981 are adhered to, while carrying out the sterilization.

9 TESTS

9.1 Visual Examination

The cutting edge of the blade shall be examined for nicks under magnification of 10X. The edge shall show no nick of size 0.10 mm or above or two nicks of sizes between 0.05 and 0.10 mm. The indentation below 0.05 mm shall not be considered for this test.

9.2 Performance Test

The blade shall be mounted on a handle conforming to this standard and with the application of light pressure, it shall be made to cut a piece of chamois leather. Five such cuts, 100 mm long approximately, shall be made. The blade shall cut the chamois leather cleanly, without pulling it. The cutting action of the blade shall be uniform through out its cutting edge.

10 MARKING

10.1 Blades

10.1.1 The blades shall be permanently marked with the following:

- a) Commercial designation of blade pattern;
- b) Indication of the source of manufacture; and
- c) The words 'Stainless Steel' or 'SS', if blades are made from stainless steel.

10.1.2 Packages of Non-sterile Blades

The primary container and the outer container for non-sterile blades shall be marked with the following:

- a) Commercial designation of blade pattern and size of fitting;
- b) Indication of the source of manufacturer;
- c) The words 'Non-sterile' in prominent lettering;

d) Quantity; and

e) The words 'Carbon Steel' or 'Stainless Steel' as the case may be.

In addition, the outer container shall also be marked with the name and complete address of the manufacturer.

10.1.3 Packages of Sterile Blades

10.1.3.1 Unit containers (primary containers) for sterile blades

These shall be marked with the following:

- a) Description of contents including commercial designation of blade pattern;
- b) The word 'Sterile' in prominent lettering;
- c) The words 'Stainless Steel' in case of blades made from stainless steel;
- d) Date of manufacture and/or batch number; and
- e) Indication of the source of manufacture.

10.1.3.2 Outer containers for sterile blades

Outer containers for sterile blades shall be marked with the following:

- a) Description of contents including quantity, commercial designation of blade pattern and size of the fittings;
- b) The word 'Sterile' in prominent lettering;
- c) The words 'Carbon Steel' or 'Stainless Steel', as the case may be;
- d) Date of manufacture and/or batch number;
- e) Date of sterilization (month and year); and
- f) Name and complete address of the manufacturer.

10.2 Handles

10.2.1 Handles shall be permanently marked with the following:

- a) The commercial designation appropriate to either small or large fittings;
- b) Indication of the source of manufacture; and
- c) The words 'Stainless Steel'.

10.2.2 Packages of Handles

The packages containing handles shall be marked with the following information:

- a) Size of fitting, that is, small size or large size;
- b) Indication of the source of manufacture; and
- c) Quantity of handles on the top of container.

10.3 BIS Certification Marking

Each package of blades and handles may also be marked with the Standard Mark.

10.3.1 The use of the Standard Mark is governed by the provisions of Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

11 PACKAGING**11.1 Packages of Non-sterile Blades****11.1.1 Unit Container**

Each blade shall be wrapped in VCI treated paper. The blade shall be individually wrapped or wrapped in such a manner that the edges are not capable of coming into contact with one another. Sealing of the blade in the unit packing should be such that the VCI treated paper and the blade shall not come within the sealing. It shall be ensured that the blade inside the unit packing remains fully covered by the VCI treated paper under normal conditions of handling and transportation.

11.1.2 Outer Container

A convenient number (preferably multiples of 10) of unit containers shall be packed in an outer container which shall be sufficiently robust to protect the contents during transit and storage.

11.2 Packages of Sterile Blades

11.2.1 Packaging of sterile blades shall satisfy the requirements of 3.5 of IS 10150 : 1981.

11.2.2 Unit Container

Each blade shall be wrapped in VCI treated paper. Each sterile blade shall be individually packed in a sealed container which shall be sufficiently robust to maintain sterility of its contents under conditions of handling and storage normally encountered in hospitals and medical practices. Sealing of the blade in the unit packing should be such that the VCI treated paper and the blade shall not come within the sealing. It shall be ensured that the blade inside the unit packing remains fully covered by the VCI treated paper under normal conditions of handling and transportation.

11.2.3 Outer Container

A convenient number (preferably multiples of 10) of unit containers shall be packed in an outer container which shall be sufficiently robust to protect the contents during transit and storage.

11.3 The primary container/unit container of blades made from stainless steel may not have VCI treated paper inside.

11.4 Packaging of Handles

Each handle may be wrapped in a moisture proof paper or put in a polyethylene bag and then packed in cardboard cartons. The handles may also be packed as agreed to between the purchaser and the supplier.

12 SAMPLING

12.1 Sampling procedure and acceptance criteria for the blades shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A

(Clause 12)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY**A-1 LOT**

A-1.1 In a consignment, all the detachable surgical blades of the same type and dimensions shall be grouped together to constitute a lot, not exceeding 50. Each lot shall be tested for the requirements of this specification.

A-2 SCALE OF SAMPLING AND CRITERIA FOR CONFORMITY

A-2.1 Eight blades from the lot shall be selected at random by using random number tables (see IS 4905 : 1968) and tested for the requirements of marking (10), packaging (11), shape and dimensions (5) and workmanship and

finish (6). Those blades having one or more defects in terms of the above requirements shall be termed defective and no defectives shall be permitted in the sample, if the lot is to be accepted under this clause.

A-2.2 The lot which has been found acceptable under A-2.1 shall then be tested for other requirements. For this purpose, three blades shall be sampled and tested for nicks (9.1), performance test (9.2) and sterility (8). One blade shall be tested for hardness (7.1). All samples shall pass the respective requirements, if the lot is to be accepted under this clause.

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition.

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Amendments Issued Since Publication

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